PA Criteria

Initial Approval: January 8, 2014
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July 9, 2014; April 9, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Direct Acting Hepatitis C Agent

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Sofosbuvir (Sovaldi®)

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT: (must meet all of the following)

Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 48 weeks of Sovaldi therapy total)

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1, 2, 3, or 4 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Sovaldi must be used in combination with ribavirin
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent (i.e. concurrent therapy or previous trial with Victrelis, Incivek, Olysio, Sovaldi, Harvoni, Viekira Pak or other direct acting Hepatitis C agent)
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 capsule per day
- Patient must have one of the following:
    - Advanced fibrosis (as defined by a Metavir score of F3)
    - Compensated cirrhosis
    - Liver transplant
    - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis)
    - Proteinuria
    - Nephrotic syndrome
    - Membranoproliferative glomerulonephritis

LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT 12 weeks

Ribavirin and peginterferon alfa are approved when using triple therapy with Sovaldi, if Sovaldi criteria are met.

RENEWAL CRITERIA FOR ONE DIRECT ACTING AGENT: (must meet one of the following)

- Patient is infected with genotype 3 CHC (an additional 12 weeks of therapy of therapy will be approved for a max of 24 weeks)
- Patient is infected with genotype 1 CHC and is ineligible to receive interferon-based therapy (an additional 12 weeks of therapy will be approved for a max of 24 weeks)
- Patient has a diagnosis of hepatocellular carcinoma and is awaiting a liver transplantation (an additional 36 weeks of therapy will be approved for a max of 48 weeks)

PA Criteria

CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF TWO DIRECT ACTING AGENTS: (must meet all of the following)

- Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 capsule per day
- Patient must not be on previous or concurrent therapy with Victrelis, Incivek, Harvoni, or Viekira Pak
- Patient must have one of the following:
    - Advanced fibrosis (as defined by a Metavir score of F3)
    - Compensated cirrhosis
    - Liver transplant
    - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis)
    - Proteinuria
    - Nephrotic syndrome
    - Membranoproliferative glomerulonephritis
- Patient must not be on previous or concurrent therapy with Olysio unless the patient is interferon ineligible defined as one or more of the following:
    - Documented intolerance to IFN
    - Autoimmune hepatitis or other autoimmune disorder
    - Documented hypersensitivity to PEG or any of its components
    - Decompensated hepatic disease
    - Major uncontrolled depressive illness
    - A baseline neutrophil count below 1500 a baseline platelet count below 90,000 or baseline hemoglobin below 10 g/dL
    - A history of preexisting cardiac disease

LENGTH OF INITIAL APPROVAL 4 weeks

RENEWAL CRITERIA FOR TWO DIRECT ACTING AGENTS: (must the following)

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents

LENGTH OF RENEWAL APPROVALS 4 weeks for a total of 12 weeks of treatment